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REMARKS

Claims 1-12 are currently pending. Claims 1 and 12 have been amended for clarification purposes as noted below. New Claims 13-36 have been added.

The Examiner rejected Claims 1-12 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,500,200 to Kushnir in view of U.S. Patent No. 5,733,319 to Neilson et al. Claims 1 and 12 have been amended to clarify that the plurality of bladders recited comprise “a plurality of generally pear-shaped lobes.” Applicants note that basis in the original disclosure for amendments to both Claims 1 and 12 can be found, for example, at paragraph [0107] of the specification and Figure 9, and is thus proper under 35 U.S.C. § 112, paragraph 1.

New independent Claim 13 recites some features included in pending Claim 1, and also recites a “plurality of inflatable bladders configured to provide a compressive force anatomically adjacent to the lactiferous sinus of a breast for the purpose of expressing intraductal fluid.” New independent Claim 24 recites some features included in pending Claim 12, and also recites “at least a first and a second inflatable bladder configured to provide a compressive force to a breast anatomically adjacent to a lactiferous sinus of a breast for the purpose of expressing intraductal fluid.” Applicants note that basis in the original disclosure for this recitation in Claim 13 and 24 can be found, for example, at paragraph [0118] of the specification, and is thus proper under 35 U.S.C. § 112, paragraph 1.

New independent Claim 25 recites some features included in pending Claim 1, and also recites “a plurality of inflatable bladders configured to provide radially symmetrical compression of a breast along a longitudinal axis for the purpose of expressing intraductal fluid.” New independent Claim 36 recites some features included in pending Claim 12, and also recites “at least a first and a second inflatable bladder configured to produce radially symmetrical compression of a breast around a longitudinal axis for the purpose of expressing intraductal fluid.” Basis in the original disclosure for this recitation in Claims 25 and 36 can be found, for example, at paragraph [0077], [0080], [0089], [0092], and [0102] of the specification, and is thus proper under 35 U.S.C. § 112, paragraph 1. As noted in the disclosure, the distal opening of the support can be radially enlarged or reduced (paragraph [0080]). An inflatable bladder 152 conforms to the radially inwardly facing walls of at least the first concavity 164, and is sandwiched between the petals 126 and patient interface 154 (paragraph [0092]). As the

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adjustability of the first concavity 164 is defined by the relative orientation of the plurality of petals 126 or other support structure (paragraph [0102]), it is evident that the bladders are thus configured for radially symmetrical compression. A longitudinal axis 168 is described in paragraph [0077] and clearly illustrated in Figure 5.

Rejections under 35 U.S.C. § 103(a)

Claims 1-12 have been rejected as unpatentable over Kushnir in view of Neilson. Although Applicants do not necessarily acquiesce to the rejections, Claims 1 and 12 have been amended herein for clarification purposes. Applicants request that the obviousness rejection be withdrawn because neither reference teaches or suggests all of the recited claim limitations as amended. Amended Claims 1 recites, inter alia, “a closed loop heating system for a nipple aspirate fluid aspiration device, comprising a plurality of inflatable bladders configured to provide compression of a breast. . . wherein said bladders comprise a plurality of generally pear-shaped lobes. . . .” Amended Claim 12 recites, inter alia, “an array of inflatable bladders for use in a breast pump, comprising: at least a first and a second inflatable bladder in a series flow path configured to provide compression of a breast. . . wherein said bladders comprise a plurality of generally pear-shaped lobes. . . .”

The Examiner found that Kushnir discloses a closed loop heating system including a plurality of inflatable bladders (Fig. 1) in a series flow path; a reservoir (90); and a fluid flow path comprising an inflow (60) and an outflow line (62) for placing the bladder in fluid communication with the reservoir (Office Action, p. 2). The Examiner found that Neilson discloses a closed loop system including a compressible reservoir (110; col. 8, l. 40) and being free of a pump, wherein the closed loop system can be operated and removed without exposing a fluid within the closed loop system to the outside of the closed loop system (col. 6, ll. 15-20)(Office Action, pp. 2-3).

Applicants submit that neither Kushnir nor Neilson teach or suggest, inter alia, bladders “comprising a plurality of generally pear-shaped lobes” as recited by amended Claims 1 and 12. In this regard, Kushnir merely teaches a garment with a variety of dedicated sections a, b, c, d, and e defined by the general shape of the garment as well as emarginations 50, 52, 54, 56, and 58 part of which are in the form of lateral indentations or in the form of slits (col. 4, ll. 43-52, Figure

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1), contrary to Claim 1 and 12's recitation of generally pear-shaped lobes. Neilson fails to make up for this deficiency. Therefore, Applicants submit the claims as amended are not obvious over the cited references.

Furthermore, Applicants also note the specification discloses special advantages of the morphology of the generally pear-shaped lobes of the inflatable bladders as claimed. The lobes 204 of an inflatable bladder 152 create a compression zone to apply a circumferential compressive force to a breast positioned therein, and facilitate intraductal fluid aspiration of a breast, as disclosed in paragraphs [0117] and [0118], and illustrated in Figure 5, and advantageously cooperate with the handpiece disclosed in the present application. The generally pear-shape of the lobes (shown in Figure 9) also allow the lobes to maintain a fairly uniform stress when under pressure (paragraph [0107]).

Because the distinct characteristics defining the inflatable bladders in the closed fluid flow loop as claimed are not taught nor suggested in the cited prior art references, Claims 1 and 12 are not obvious over the aforementioned references. We thus request that the Examiner withdraw this rejection. Applicants note that Claims 2-11 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

Allowability of New Claims 13-24

Applicants submit that new Claims 13-24 are also allowable over the references cited, and are properly supported by the disclosure, as noted above. Neither Kushnir nor Neilson teaches or suggests, inter alia, bladders "configured to provide a compressive force anatomically adjacent to the lactiferous sinus of a breast for the purpose of expressing intraductal fluid." Applicants submit that Kushnir's device, which includes four thin sheets 305, 306, 307, 308 (Fig. 3A) closely spot-welded together (col. 2, ll. 35-40) and divided into sections, is not configured for compression of a breast as claimed. Kushnir's heat-exchanging device is designed for a different application than Applicant's device: to control a patient's body temperature, enveloping a substantial surface area of the patient's body. Thus, Applicants submit that one of ordinary skill in the art would not be motivated to modify Kushnir's device as claimed. Even assuming arguendo that the sections of Kushnir can be modified for breast compression, Applicants submit

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that any compression provided (e.g., the embodiment of Fig. 4), would be along an anterior-posterior axis which would not facilitate expression of intraductal fluid from the lactiferous sinus, and would be contrary to the recitation that the compressive force is “anatomically adjacent to the lactiferous sinus for the purpose of expressing intraductal fluid” as claimed. Neilson, which merely discloses a balloon 34 that serves to retain shaft 32 in a fixed position within the urethra (col. 4, ll. 55-65), does not make up for this deficiency. Thus, Applicants submit that Claim 13 and 24 are allowable over the cited reference. Claims 14-23 depend from Claim 13 and recite all of the features thereof in addition to further distinguishing features; thus Applicants submit that these claims are also allowable.

Allowability of New Claims 25-36

Applicants submit that new Claims 25-36 are also allowable over the references cited, and are properly supported by the disclosure, as noted above. Neither Kushnir nor Neilson teaches or suggests, inter alia, bladders “configured to provide radially symmetrical compression of a breast along a longitudinal axis for the purpose of expressing intraductal fluid.” As noted in the discussion of Claims 13-24 above, Kushnir’s heat-exchanging device is designed for a different application than Applicant’s device: to control a patient’s body temperature, enveloping a substantial surface area of the patient’s body. Thus, Applicants submit that one of ordinary skill in the art would not be motivated to modify Kushnir’s device as claimed. Even assuming arguendo that the sections of the device of Kushnir can be modified for breast compression, Applicants submit that any compression provided by Kushnir’s device (e.g., the embodiment of Fig. 4) would be along an anterior-posterior axis which would not facilitate expression of intraductal fluid, and would be contrary to the recitation that the bladders are “configured to provide radially symmetrical compression of a breast along a longitudinal axis for the purpose of expressing intraductal fluid.” Neilson fails to make up for this deficiency. Thus, Applicants submit that Claim 25 and 36 are allowable over the cited reference. Claims 26-35 depend from Claim 25 and recite all of the features thereof in addition to further distinguishing features; thus Applicants submit that these claims are also allowable.

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CONCLUSION

For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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